Application No.: 09/822,126
Response Dated: July 5, 2006
Reply to Office Action of: January 9, 2006

REMARKS

Claims 1-12, 19-23, 25-28, 30, 36-48, 58-65, 67-79, and 81 are pending. Claims 1, 5-12, 30, 36-39, 67-72, and 81 remain under consideration in the case. Of the pending claims, claims 2-4, 19-23, 25-28, 40-48, 58-65, and 73-79 have been withdrawn by the Examiner. [Paper No. 010406 at 1-2].

Claims 13-18, 24, 29, 31-35, 49-57, 66, and 80 have been cancelled, without prejudice.

I. Rejections Under 35 USC §102(b)

A. Mansat, US Patent No. 4,728,329

Claims 1, 5-12, and 67-72 were rejected under 35 USC §102(b) as anticipated by Mansat, US Patent No. 4,728,329 ("Mansat"). [Paper No. 010406 at 2].

For the reasons set forth below, this rejection is respectfully traversed.

Initially, we note that the rejection of claims 30 and 36-39 under 35 USC §102(b) over Mansat made in the previous Office Action (*see* Paper No. 040505 at 4) has not been repeated in the present Office Action. Thus, we assume that the rejection of claims 30 and 36-39 over Mansat has been withdrawn.

Mansat discloses "a prosthetic band which is capable of use as a prosthetic tendon." [Column 1, lines 5-6]. Mansat exemplifies the prosthetic band as a "transverse or cruciate ligament of a knee joint." [Column 2, lines 23-24].

Mansat discloses that the structure of the prosthetic band "is comprised of a plurality of concentric sleeve-like elements which define a shaft having a central flexible zone and a pair of rigid end zones." [Column 1, lines 51-53]. With reference to Figure 1, Mansat discloses that "the band 1 has a central flexible zone 1*a* of a diameter D which merges at each end into a rigid end zone 1*b* of a diameter d. To this end, each end zone 1*b* has a relatively reduced flexibility with respect to the central zone 1*a*. ... The band 1 also has thin leader parts 1*c* extending from each rigid zone 1*b*." [Column 3, lines 3-7 and 17-18]. Figure 1 is reproduced below:

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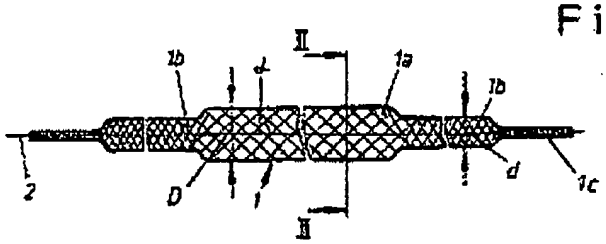
Fig.1



Mansat also discloses that the band is secured to a bone by "hammering" a "brace" or an "agraffe" "*through an end zone* ... into the bone." [*See*, Column 3, line 62 - Column 4, line 2; *see also*, Column 2, lines 32-56 and Fig. 3 (emphasis added)]. Fig. 3 is reproduced below:

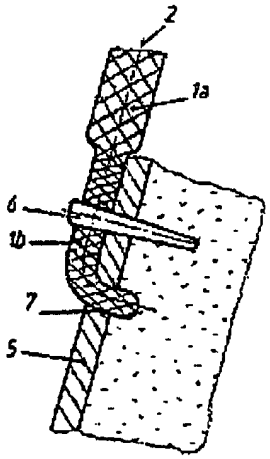


Fig.3

In making the rejection, the Examiner asserted that "Mansat discloses a connection system comprising a ligament and first and second bone fasteners. The ligament is made of a braided fabric and includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion. The fasteners may be shoulderless." [Paper No. 010406 at 2].

With specific reference to Fig. 3 of Mansat, the Examiner further asserted that the end portions are dimensioned to cooperatively connect with the bone fasteners.

> Note that the shape of the end portions is such that they ***cooperate to connect*** with the bone fasteners. The claim requires nothing more. [*Id.* at 3 (emphasis added)].

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir. 1984).

Independent claims 1 and 67 each recite that the first and second "end portions" of the "ligament" are shaped to "*cooperatively connect*" to the first and second "bone fasteners," respectively. The term "cooperatively connect" is defined in the specification to mean that the ligament connects to the bone fasteners in a "non-destructive way."

> 'Cooperative connection' means the components connect in ***a non-destructive way*** without the use of sutures. [Page 8, lines 11-12 (emphasis added)].

The rejection does not - and cannot - identify *any* disclosure in Mansat that the band is secured to the bone in a "***non-destructive way***" as recited in claims 1 and 67. Indeed, Mansat discloses just the opposite (*see, e.g.*, column 3, lines 62-64 and Fig. 3), *i.e.*, a ***destructive way*** of securing the band to the bone by hammering a "brace" or "agraffe" "***through***" the band and into the bone.

> Referring to FIG. 3, in order to secure the prosthetic band 1 to a bone 5, a brace or agraffe 6 is ***hammered through*** an end zone 1a into the bone 5 in order to secure the rigid zone 1b to the bone 5. At a few centimeters outside the agraffe 6, the rigid zone 1b is severed by a sharp cutting tool, such as a scalpel, and recessed into a previously provided bore 7 in the bone 5. With the opposite end secured in like manner, the band 1 can be firmly secured in place. [Column 3, line 62 - Column 4, line 2 (emphasis added)]

Thus, because the rejection fails to identify in Mansat "cooperatively connecting," *i.e.*, connecting in a "non-destructive way," first and second ends of the ligament to the first and second bone fasteners as recited in claims 1 and 67, the rejection must fail.

Accordingly, for the reasons set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 5-12, and 67-72.

B. Yuan and Lin, US Patent No. 5,681,310

Claims 1, 5, 7-9, 11, 12, 30, 36-39, 67-69, 71, and 72 were rejected under 35 USC §102(b) as anticipated by Yuan and Lin, US Patent No. 5,681,310 ("Yuan"). [Paper No. 010406 at 4].

For the reasons set forth below, this rejection is respectfully traversed.

Yuan discloses "[a] vertebral auxiliary fixation device [that] comprises a holding mat and a plurality of fastening elements." [Abstract]. Yuan discloses that the device is "capable of holding an implanted graft or filling." [Column 1, lines 9-11].

Yuan discloses that both the holding mat and the fastening elements "may be made of a biocompatible material." [Column 2, lines 22-27]. Yuan exemplifies "Dacron" as a "biocompatible material." [Column 1, lines 61-63].

Yuan discloses that the fastening elements may be "screws," "hooks," or "staple shaped." [Column 2, lines 5-10; Column 3, line 22-23; and Figs. 2-6]. Yuan also discloses that the holding mat is secured to a vertebrae by inserting a plurality of the "fastening elements" *through* the mat and into the vertebrae. [*See, e.g.*, Column 2, lines 5-14; Figs. 1-6; and claim 1].

1. The Rejection Of Claims 1, 5, 7-9, 11, 12, 67-69, 71, And 72 Should Be Withdrawn

In making the rejection, the Examiner asserted that Yuan discloses "an intervertebral connection system comprising a ligament 10 and first and second bone fasteners 20 .... The ligament is made of a fabric such as DACRON ... and includes a central portion, first and second end portions and first and second conformable portions disposed between the end portions and the central portion." [Paper No. 010406 at 5]. The Examiner further asserted that the "mat is flexible" and that "all the portions would be 'conformable.'" [*Id.*].

With respect to claim 1, the Examiner asserted that Yuan discloses that the end portions "cooperatively connect" with the bone fasteners.

> The end portions have a shape such that they ***cooperatively connect*** with the bone fasteners, *i.e.* via a hole. [*Id.* (emphasis added)].

All that the rejection has to say about claim 67 is that:

> [T]he first and second conformable portions above constitute the first and second intermediate portion. [*Id.* at 6].

As noted above, anticipation requires "identity of invention." *Glaverbel Societe Anonyme,* 33 USPQ2d at 1498. Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *Marshall*, 198 USPQ at 346; *Lindemann Maschinenfabrik*, 221 USPQ at 485.

Independent claims 1 and 67 each recite that the first and second "end portions" of the "ligament" are shaped to "*cooperatively connect*" to the first and second "bone fasteners," respectively. As noted above, the term "cooperatively connect" is defined in the specification to mean that the ligament connects to the bone fasteners in a "***non-destructive way***." [Page 8, lines 11-12 (emphasis added)].

The rejection does not - and cannot - identify *any* disclosure in Yuan that the holding mat 10 is secured to the bone in a "***non-destructive way***" as recited in claims 1 and 67. Indeed, Yuan discloses just the opposite (*see, e.g.*, column 2, lines 5-14; column 3, lines 5-10; and Fig. 1), *i.e.*, a ***destructive way*** of "securing the holding mat to the bone by inserting a plurality of fastening elements ***through*** the flexible biocompatible material" (*see, e.g.*, claim 1).

Thus, because the rejection fails to identify in Yuan "cooperatively connecting," *i.e.*, connecting in a "non-destructive way" first and second ends of the ligament to the first and second bone fasteners as recited in claims 1 and 67, the rejection must fail. Accordingly, for the reasons set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 5, 7-9, 11, 12, 67-69, 71, and 72.

2. The Rejection Of Claim 30 Should Be Withdrawn

The rejection is completely silent as to independent claim 30 except to indicate that it is anticipated by Yuan. Indeed, the rejection makes no attempt to explain where each and every element of claim 30 is found in Yuan. Thus, the rejection of claim 30 does not rise to the level of a *prima facie* case and must be withdrawn for this reason alone.

Although Applicants have no burden to do so, with a view toward furthering prosecution, we describe below at least one reason why Yuan does not disclose each and every element of claim 30. Claim 30 recites that "the bone fastener is made of a bioresorbable PLA/PLG copolymer...." Simply put, the Examiner did not - and cannot - identify where Yuan discloses that the so-called "fastening elements" are made of a "bioresorbable PLA/PLG copolymer" as recited in claim 30.

Although Yuan discloses that the holding mat and fastening elements may be made of "a biocompatible material," (*see, e.g.*, column 2, lines 22-24), the only exemplified material is DACRON (*see, e.g.*, column 1, lines 61-63). It is respectfully submitted that neither the generic disclosure of "biocompatible material" nor the specific disclosure of "DACRON" is a disclosure of "a bioresorbable PLA/PLG copolymer" as recited in claim 30. Thus, Yuan does not disclose each and every element of claim 30. Accordingly, withdrawal of the rejection of claim 30 is respectfully requested for this additional reason.

3. The Rejection Of Claims 36-39 Should Be Withdrawn

The rejection is also completely silent as to independent claim 36 (and claims 37-39, which depend therefrom) except to indicate that claims 36-39 are anticipated by Yuan. Indeed, the rejection makes no attempt to explain where each and every element of claims 36-39 is found in Yuan. Thus, the rejection of claims 36-39 does not rise to the level of a *prima facie* case and must be withdrawn for this reason alone.

Although Applicants have no burden to do so, with a view toward furthering prosecution, we describe below at least one reason why Yuan does not disclose each and every element of claim 36. Claim 36 recites that the first and second bone fasteners are

"pre-connected" to the first and second end portions of the ligament. The specification defines "pre-connected" to mean that "two components are attached ***prior to*** their placement upon the spine." [*See*, p. 8, lns. 8-9 (emphasis added)]. The Examiner did not - and could not - identify any portion of Yuan that discloses such an arrangement.

Simply put, Yuan does not disclose bone fasteners "pre-connected" (*i.e.*, that are attached) to a ligament ***prior*** to placement of the ligament onto the spine, as recited in claim 36. Rather, Yuan discloses a mat wherein the fasteners are connected to the spine through the mat ***after*** positioning the mat over the spine. [*See, e.g.*, Column 2, lines 5-14; Figs. 1-6; and claim 1]. Claim 1 of Yuan exemplifies such a device and is representative of all the disclosed embodiments.

> ... covering an outer side of the foreign object with a mat made from a flexible, biocompatible material; and
>
> ***fastening the mat in place by inserting a plurality of fastening elements through the flexible biocompatible material and into the vertebra*** to prevent the foreign object from jutting out of the vertebra. [Claim 1 (emphasis added)].

Thus, Yuan does not disclose each and every element of claim 36. Accordingly, withdrawal of the rejection of claims 36-39 is respectfully requested.

In sum, for the reasons set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 1, 5, 7-9, 11, 12, 30, 36-39, 67-69, 71, and 72.

II. Rejection Under 35 USC §103(a)

A. Mansat, US Patent No. 4,728,329

Claims 30 and 81 were rejected under 35 USC §103(a) as unpatentable over Mansat. [Paper No. 010406 at 6].

For the reasons set forth below, this rejection is respectfully traversed.

Mansat is summarized above.

In making the rejection, the Examiner acknowledged that Mansat does not disclose an intervertebral connection system wherein the "bone fastener is made of a

bioresorbable PLA/PLG copolymer." [*Id.*]. To fill this acknowledged gap, the Examiner asserted that "[i]t would have been obvious ... to make ***the device*** of PLA/PLG copolymer." [*Id.* (emphasis added)]. The Examiner contended that support for this position is found in *In re Leshin*, 125 USPQ 416 (CCPA 1960), which according to the Examiner stands for the proposition that it is within the "skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." [Paper No. 010406 at 6].

Initially, we note that the rejection is factually inaccurate. The rejection asserts that "it would have been obvious ... to make ***the device*** of PLA/PLG copolymer ...." [*Id.*]. Claim 30 does ***not*** recite that "the device" is made of a PLA/PLG copolymer. Rather, claim 30 recites that the bone fasteners, which are part - but not the entirety - of the intervertebral connection system, are made of a bioresorbable PLA/PLG copolymer. Accordingly, because the rejection is based on something other than what is claimed, it must be withdrawn for this reason alone.

Moreover, the Examiner's reliance on *Leshin* is misplaced. In *Leshin* five different references were relied on (Root, Gleeson, Anderson, Mahruki, and Gahide). *Leshin*, 125 USPQ at 417. Root, the apparent primary reference, disclosed a metal lip stick container, but did not disclose, *inter alia*, the use of molded plastic material for the body of the claimed "liquid-tight and air tight container dispenser for cosmetics in a solid stick form." [*Id.*]. The CCPA found, however, that Anderson, one of the secondary references, disclosed "a similar container of molded plastic." [*Id.* at 417-418]. Thus, in *Leshin*, the Examiner presented evidence, in the form of statutory prior art, showing the interchangeability of metal and molded plastic for cosmetic containers. These are not the present facts.

Here, the Examiner has identified no evidence, prior art or otherwise, to suggest that one skilled in the art would have considered "bioresorbable PLA/PLG copolymers" to be interchangeable with the undisclosed materials used to make the fasteners in Mansat. Indeed, the present record is more like the facts in *Ex parte Tsai*, 2003 WL 23014461 (BPAI 2003) (unpublished), which rejected the Examiner's attempt to rely on *Leshin* without providing evidence of the interchangeability of certain claimed

naphthalene-containing polymers in a multilayer flat film structure for certain other polyesters disclosed in the prior art. The Board admonished the Examiner in *Tsai* that:

> The present case differs from *Leshin* in that the record does not indicate that it was known in the art that the naphthalene-containing polymers of Kemski or Nägeli have suitable properties, *i.e.*, the required strength and ability to be adhesive bonded to a fluoropolymer, for use in Kim's multilayer film. The examiner points out (answer, page 6) that Kim's thermoplastic polymers include polyesters (col. 3, lines 16-22), but has not established that naphthalene-containing polyesters have properties which would have led one of ordinary skill in the art to consider them to be suitable as substitutes for the polyesters disclosed by Kim. It is not sufficient to merely assert, as the examiner has done (answer, page 6), that Kim's polyesters and the naphthalene-containing polyesters of Kemski and Nägeli are similar. [*Id.* at *2].

On the present record, the facts here are even worse than those in *Tsai* where the Board *reversed* the Examiner for relying on *Leshin*. In *Tsai*, the Examiner at least made of record two secondary references that disclosed the claimed naphthalene-containing polyesters. Here, the record is silent as to what one skilled in the art would have known about the use of "bioresorbable PLA/PLG copolymers" to make bone fasteners. Here too, the record is silent as to the interchangeability of such copolymers for the undisclosed materials used to make the fasteners in Mansat. In view of the foregoing, the Examiner's reliance on *Leshin* is misplaced. For this reason also, it is respectfully submitted that the rejection should be withdrawn.

Tsai does not stand alone. It is consistent with long settled precedent, which holds that obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993).

As summarized above, the Examiner has made no factual determination regarding the composition disclosed for the Mansat fasteners (*i.e.*, "brace" or "agraffe"). Nor has the Examiner made any factual determination regarding the state-of-the-art with respect

to materials used for bone fasteners. Nor has the Examiner made any factual determination regarding the interchangeability of the Mansat fasteners for the bone fasteners made of a "bioresorbable PLA/PLG copolymer" as recited in claim 30.

In short, the rejection is based on the unsupported conclusion that a bone fastener made of a "bioresorbable PLA/PLG copolymer" as recited in claim 30 is interchangeable with a "brace" or "agraffe" made from an unidentified material as disclosed in Mansat. As noted above, however, a rejection that is not based on facts cannot stand. *Saceman*, 27 USPQ2d at 1474. For this reason also, it is respectfully submitted that the rejection of claims 30 and 81 should be withdrawn.

We further note that an Examiner's belief or conjecture is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) *citing*, *In re Antonie*, 195 USPQ 6 (CCPA 1977). ("We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art."). Because the rejection has substituted conjecture as to what one skilled in the art would believe for the required statutory reference, for this additional reason the rejection of claims 30 and 81 should be withdrawn.

With respect to the rejection of claim 81, there are independent additional reasons why the rejection should be withdrawn. First, we note that claim 81 depends from claim 30 and recites not only that the intermediate portions of the ligament be "conformable" (*i.e.*, first and second conformable portions disposed between the central portion and the first and second end portions, respectively), but also that the bone fasteners be "connected" to the end portions of the ligament.[1/] The rejection, however, fails to make any factual determination as to the presence or absence of these elements in Mansat as is clearly required to make out a *prima facie* case. *Saceman*, 27 USPQ2d at 1474. For this reason also the rejection of claim 81 should be withdrawn.

Assuming *arguendo*, that the rejection is legally sufficient, which it is not, we note that there are factual gaps in Mansat, which undermine the rejection. For example, claim 81 recites not only that the intermediate portion of the ligament be "conformable,"

1/ The specification defines a "conformable" portion of a ligament to mean that that "portion of the ligament can be bent approximately 90°, more preferably approximately 120°, around a corner ...." [*See*, page 7, lns. 24-25].

but also that the bone fasteners be connected to the end portions of the ligament. Mansat, however, discloses a central portion 1a, end portions 1c and intermediate portions 1b, wherein the intermediate portions are ***rigid***. [*See*, Column 3, line 65]. In short, Mansat does ***not*** disclose a conformable intermediate portion as recited in claim 81, but rather discloses the opposite. In view of this unexplained factual gap between Mansat and claim 81, the rejection is deficient and should be withdrawn.

Thus, for the reasons set forth above, withdrawal of the rejection of claims 30 and 81, respectfully is requested.

CONCLUSION

For the reasons set forth above, reconsideration and withdrawal of all rejections are respectfully requested.

Should there be any remaining or further questions, the Examiner is requested to please contact the undersigned directly.

Respectfully submitted,

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